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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,643	12/12/2001	Michael O. Thorner	033493-001	9752

21839 7590 10/28/2005

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EXAMINER	
KAUFMAN, CLAIRE M	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,643	THORNER ET AL.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7 and 15* is/are pending in the application.

4a) Of the above claim(s) *5 and 6* is/are withdrawn from consideration.

5)☒ Claim(s) *15* is/are allowed.

6)☒ Claim(s) *7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *5,6 and 15* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/10/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Newly amended claims 5 and 6 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the amendment changed the SEQ ID NO: in these claims so they are drawn to the GHRH ligand instead of the elected inventions: the GHRH receptor polypeptide.

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 5 and 6 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

The rejection of claims under 35 USC 102(b) is withdrawn in view of the amendment to the claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: No basis could be found for the amendment of claim 7 which added the limitation that the polypeptide can differ from SEQ ID NO:4 by one or more conservative amino acid substitutions. The specification on page 7, lines 2-7, recites that one or more conservative amino acids of SEQ ID NO:1 may be substituted while retaining GHRH activity, but no basis for conservative substitutions of SEQ ID NO:4 while retaining GHRH receptor activity (*i.e.*, GHRH binding ability) could be found.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

Claim 7 remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a GHRH receptor having the amino acid sequence of SEQ ID NO:4, does not reasonably provide enablement for other GHRH receptors which bind human and chicken GHRH. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the reasons set forth in the previous Office action and those related to the claim amendment as follows:

As amended, claim 7 includes a polypeptide which differs from SEQ ID NO:4 by one or more conservative amino acid substitutes and which binds human GHRH and the chicken GHRH polypeptide of SEQ ID NO:2. This claim encompasses a polypeptide with a sequence completely different from SEQ ID NO:4 which has the required activity. With the amendment, it continues to resemble a single means claim as discussed in MPEP 2164.08(a), *i.e.*, where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. In re Hyatt, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. In the instant case, there is no disclosure of a GHRH receptor with the required function other than that of SEQ ID NO:4. While there is high sequence conservation among mammalian GHRH receptors, this conservation does not extend to chickens (p. 2, lines 1-5 of specification). Amino acid comparisons show only a 40-60% conservation of amino acids of SEQ ID NO:4 to other common mammal GHRH receptor protein sequences (see attached listing of sequence comparisons results). There is no description of what structural properties make the receptor of SEQ ID NO:4 able to bind both human GHRH and chicken GHRH of SEQ ID NO:2. There is no guidance for altering SEQ ID NO:4 in a manner that maintains the binding function. The prior art also fails to provide information in the form of guidance or examples to allow the

skilled artisan to make a GHRH receptor having the required binding activity. For these reasons which include the structural breadth of the claim and lack of functional limitation, the complexity of the art related to existence and function of a chicken GHRH receptor, and the lack of guidance and examples about the existence and/or making of a chicken GHRH receptor other than SEQ ID NO:4, it is maintained for the reasons of record and as discussed here, that it would require undue experimentation to make the instant invention commensurate in scope with the claims.

Applicants argue that Examples 1 and 3 of the specification provide sufficient direction and examples to support the breadth of claim 7 as it relates to a GHRH receptor with a sequence different than but related by conservative amino acid substitutions to SEQ ID NO:4. The argument has been fully considered, but is not persuasive. For the reasons discussed above, the new claim limitations allow breadth so great that the polypeptide need not have a sequence shared by the only disclosed chicken GHRH receptor, while requiring functional limitations of the claimed polypeptide. It is maintained that neither the prior art nor specification, alone or in combination, is enabling for the scope of the claim (see immediately above).

Claim 7 as amended remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection has been recast here to address the amendment to the claim.

The claim is drawn to polypeptide which differs from SEQ ID NO:4 by one or more conservative amino acid substitutes and which binds human GHRH and the chicken GHRH polypeptide of SEQ ID NO:2. The claims do not require that the polypeptide possess any particular conserved structure or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that is defined very broadly by structure with two required binding functions. Also, it is noted that no basis in the specification could be found for a

polypeptide comprising an amino acid sequence that differs from SEQ ID NO:4 by one or more conservative amino acid substitutions.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of including any conservative amino acid substitutions in SEQ ID NO:4 combined with a binding function. There is not identification of any particular portion of the structure that must be conserved. The GHRH receptor of SEQ ID NO:4 does not share a highly conserved sequence with other known and characterized GHRH receptors that would allow the skilled artisan to reasonably predict which amino acids could be substituted while maintaining the required function. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Which polypeptides of the genus comprising the required sequence are part of the invention has not been set forth.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to

lack of written description for that broad class. The specification provided only the bovine sequence. In this instance, only a single chicken GHRH receptor has been described, not a broad class of proteins having the ability to bind chicken GHRH of SEQ ID NO:2 and human GHRH.

Therefore, only SEQ ID NO:4, but not the full breadth of the claim meets the written description provision of 35 U.S.C. § 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see page 1115).

Applicants urge that the added limitation to the claim obviates the written description rejection. The argument has been fully considered, but is not persuasive. As amended, the claims are drawn to a large genus of polypeptides with a required function. However, the specification has not provided guidance about the structure/function relationship to allow the skilled artisan to reasonably predict what changes could be made to SEQ ID NO:4 while maintaining the required function that has been shown to belong only to the receptor of SEQ ID NO:4. Because of the low structural conservation between chicken GHRH receptor and other known GHRH receptors and lack of guidance in the specification, the specification has not provided sufficient distinguishing identifying characteristics of the genus to support the assertion that at the time the application was filed the inventors had possession of the claimed invention as it is currently broadly claimed.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,973,114 shares some of the same inventors of the instant application and claims a GHRH receptor of approximately 55 kDa. The patent's claimed receptor was isolated from ovine and bovine. Because no chicken receptor was isolated in the patent, it was subsequently shown to be difficult to isolate and there is not high sequence conservation between chicken and other species' GHRH receptor, the patent does not anticipate or render obvious the claimed invention.

Conclusion

Claim 15 is allowable over the prior art.

Applicant's amendment necessitated the recast ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571) 272-0873. Dr. Kaufman can generally be reached Monday, Tuesday, Thursday and Friday from 9:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (571) 272-0829.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (571) 273-8300. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Claire M. Kaufman, Ph.D.
Patent Examiner, Art Unit 1646
October 20, 2005

LORRAINE SPECTOR
PRIMARY EXAMINER

SUMMARIES-SEQ ID NO:4

Result No.	Score	Query Match	Length	DB	ID	Description
1	1419.5	62.5	423	1	GRFR_HUMAN	Q02643 homo sapien
2	1366.5	60.1	423	1	GRFR_PIG	P34999 sus scrofa
3	1365	60.1	423	2	Q9BDH9	Q9bdh9 bos taurus
4	1360	59.9	423	2	Q9N1F8	Q9n1f8 bos taurus
5	1339	58.9	441	2	Q9TUJ0	Q9tuj0 bos taurus
6	1313	57.8	407	2	Q9BDI0	Q9bdi0 ovis aries
7	1297	57.1	439	2	Q9WU99	Q9wu99 rattus norv
8	1279.5	56.3	464	1	GRFR_RAT	Q02644 rattus norv
9	1274.5	56.1	464	2	Q6LEF5	Q6lef5 rattus sp.
10	1274	56.1	423	1	GRFR_MOUSE	P32082 mus musculu
11	1266.5	55.7	404	2	Q9TUJ1	Q9tuj1 bos taurus
12	1198	52.7	359	2	Q9HB45	Q9hb45 homo sapien
13	1035	45.6	459	1	VIPR_MOUSE	P97751 mus musculu
14	1012	44.5	459	1	VIPR_RAT	P30083 rattus norv
15	1002.5	44.1	444	2	Q9YHC6	Q9yhc6 rana ridibu
16	994	43.8	438	2	Q8AXV2	Q8axv2 fugu rubrip
17	987	43.4	465	2	Q9PTK1	Q9ptk1 xenopus lae
18	983	43.3	457	1	VIPR_HUMAN	P32241 homo sapien
19	980.5	43.2	459	2	Q8BGA4	Q8bga4 m mus muscu
20	980.5	43.2	468	2	Q6NXJ9	Q6nxj9 mus musculu
21	977.5	43.0	468	1	PACR_HUMAN	P41586 homo sapien
22	977	43.0	457	2	Q6P2M6	Q6p2m6 homo sapien
23	975	42.9	455	2	Q90Y10	Q90y10 rana ridibu
24	974	42.9	438	2	O73768	O73768 carassius a
25	973	42.8	458	1	VIPR_PIG	Q28992 sus scrofa
26	972.5	42.8	465	2	O73769	O73769 carassius a
27	**968**	**42.6**	**418**	**2**	**Q9IBG2**	**Q9ibg2 gallus gall**
28	963.5	42.4	457	2	Q64FL5	Q64fl5 oncorhynchu
29	960	42.3	447	1	VIPR_CARAU	Q90308 carassius a
30	960	42.3	457	1	VIPR_MELGA	Q91085 meleagris g
31	956.5	42.1	496	1	PACR_MOUSE	P70205 mus musculu
32	955.5	42.1	513	1	PACR_BOVIN	Q29627 bos taurus
33	953	41.9	440	1	SCRC_HUMAN	P47872 homo sapien
34	953	41.9	440	2	Q8IV17	Q8iv17 homo sapien